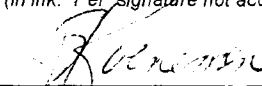
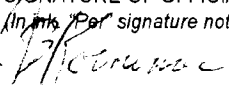


## EXHIBIT C

Form Approved Through 05/2004  
OMB No. 0925-0001

Department of Health and Human Services Public Health Services <b>Grant Application</b> <i>Follow instructions carefully.</i> <i>Do not exceed 56-character length restrictions, including spaces.</i>		<b>LEAVE BLANK—FOR PHS USE ONLY.</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;">Type</td> <td style="width:33%;">Activity</td> <td style="width:33%;">Number</td> </tr> <tr> <td colspan="2">Review Group</td> <td>Formerly</td> </tr> <tr> <td colspan="2">Council/Board (Month, Year)</td> <td>Date Received</td> </tr> </table>		Type	Activity	Number	Review Group		Formerly	Council/Board (Month, Year)		Date Received
Type	Activity	Number										
Review Group		Formerly										
Council/Board (Month, Year)		Date Received										
1. TITLE OF PROJECT <b>Development of a Massed Practice Stroke Therapy Device</b>												
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (If "Yes," state number and title) Number: <b>PHS 2002-2</b> Title: <b>SBIR</b>												
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		New Investigator <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes										
3a. NAME (Last, first, middle) <b>Koeneman, James, Bryant</b>		3b. DEGREE(S) <b>BSME MS PhD</b>										
3c. POSITION TITLE <b>President</b>		3d. MAILING ADDRESS (Street, city, state, zip code) <b>1949 East Broadway Road, Suite D Tempe, AZ 85282</b>										
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT												
3f. MAJOR SUBDIVISION												
3g. TELEPHONE AND FAX (Area code, number and extension) TEL: <b>(480)557-0448</b> FAX: <b>(480) 557-0449</b>		E-MAIL ADDRESS: <b>jkoeneman@kineticmuscles.com</b>										
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes		5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes										
4a. Research Exempt <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," Exemption No. _____		5a. If "Yes," IACUC approval Date										
4b. Human Subjects Assurance No. <b>None</b>		5b. Animal welfare assurance no										
4c. NIH-defined Phase III Clinical Trial <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes												
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY) From <b>04/01/03</b> Through <b>09/30/03</b>		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) <b>\$100,000</b>										
		7b. Total Costs (\$) <b>\$100,000</b>										
		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 8a. Direct Costs (\$) <b>\$100,000</b>										
		8b. Total Costs (\$) <b>\$100,000</b>										
9. APPLICANT ORGANIZATION Name <b>Kinetic Muscles, Inc.</b> Address <b>1949 East Broadway Road, Suite D Tempe, AZ 85282</b>  Institutional Profile File Number (if known)		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input checked="" type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged  11. ENTITY IDENTIFICATION NUMBER <b>EIN 86-1031432</b> DUNS NO. (if available)  Congressional District <b>1</b>										
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name <b>Jame B. Koeneman</b> Title <b>President</b> Address <b>1949 East Broadway Road Tempe, AZ 85282</b>  Tel <b>(480) 557-0448</b> FAX <b>(480) 55-0449</b> E-Mail <b>jkoeneman@kineticmuscles.com</b>		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name <b>James B. Koeneman</b> Title <b>President</b> Address <b>1949 East Broadway Road Tempe, AZ 85282</b>  Tel <b>(480) 557-0448</b> FAX <b>(480) 557-0449</b> E-Mail <b>jkoeneman@kineticmuscles.com</b>										
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PD NAMED IN 3a. (Ink. Per signature not acceptable.) 										
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. (Ink. Per signature not acceptable.) 										
		DATE <b>7/24/02</b>										
		DATE <b>7/24/02</b>										

**DESCRIPTION:** State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

Stroke (CVA) is the leading cause of disability in the United States and it is estimated that its prevalence will more than double over the next 50 years. Current stroke therapy is labor-intensive and costly. The United States spends \$17 billion taking care of stroke survivors. Recently, concentrated, massed practice therapies have been developed that improve function in CVA patients by reversing the effects of "learned nonuse". The objective of this project is to investigate the feasibility of a device that facilitates the administration of massed practice stroke therapy. The long-term objective is to provide a lightweight device for home use that provides motion and biofeedback of desired and undesirable muscle activity. Software controls the function of the device and monitors patient progress and compliance. A pneumatic artificial muscle will be used to provide physical motion. This artificial muscle has many of the properties of human muscle. It is lightweight, flexible and has spring like properties. This project will focus on treating wrist and finger extensor weakness, however, the concept applies to all areas affected by motor impairment. This Phase I study includes detailed design verification measurements on the device and measures the responses of able bodied test subjects to the treatment protocol.

**PERFORMANCE SITE(S)** (organization, city, state)

Kinetic Muscles, Inc. Tempe, AZ

Barrow Neurological Institute at St. Joseph's Hospital and Medical Center, Phoenix, AZ

**KEY PERSONNEL.** See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	Organization	Role on Project
Koeneman, James B.	Kinetic Muscles, Inc.	P.I.
Eblen, Cristobel	Southwest Behavioral Health Center	Statistical Consultant
Herring, Donald	Arizona State University	Human Factors, Indus Des.
Koeneman, Edward	Kinetic Muscles, Inc.	Device design & fabrication
Kwasnica, Christina	Barrows Neurological Institute	Physician evaluation
Wendelboe, Douglas	Kinetic Muscles, Inc.	Software & firmware design
Wolf, Steven	Emory University	Therapy consultant

**Disclosure Permission Statement.** Applicable to SBIR/STTR Only. See instructions. ☒ Yes

☐ No

# EXHIBIT C

Principal Investigator/Program Director (Last, First, Middle): Koeneman, James, Bryant

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

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### Appendix (*Five collated sets. No page numbering necessary for Appendix.*)

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.

Number of publications and manuscripts accepted for publication (*not to exceed 10*)

Other items (list)

☐

Check if  
Appendix is  
Included

# EXHIBIT C

Principal Investigator/Program Director (Last, first, middle):

Koeneman, James, Bryant

BUDGET JUSTIFICATION PAGE MODULAR RESEARCH GRANT APPLICATION				
Initial Budget Period	Second Year of Support	Third Year of Support	Fourth Year of Support	Fifth Year of Support
\$ 100,000.00	\$	\$	\$	\$
Total Direct Costs Requested for Entire Project Period			\$ 100,000.00	

## Personnel

During the 6 months of this project, the P.I. will have 30% effort. He will coordinate activities, manage the budget and provide biomechanical analysis. Edward Koeneman will have 30% effort during the 6 months. He will be responsible for hardware design, test and assembly of the devices to be used in the pilot study. Douglas Wendelboe will have 30% effort during the 6 months of the project and will be responsible for programming and data retrieval.

## Consortium

Dr. Kwasnica will assist in selecting the clinical participants in the pilot study and participate in the performance and evaluation of the results of the pilot study. Payment to the clinician and caregiver pilot study participants is budgeted to be \$14,000. The statistical consulting of Dr. Eblen plus the Human Factors consulting of Donald Herring and Dr. Kwasnica's consulting are estimated to be \$10,000. Dr. Steven Wolf from Emory University will consult on concentrated practice, therapy protocols, and evaluation of results at no cost to the grant.

## Fixed Fee (SBIR/STTR Only)

None

## BIOGRAPHICAL SKETCH

NAME		POSITION TITLE	
James B. Koeneman		Senior Biomechanics Consultant	
EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Minnesota, Minneapolis, MN	BSME	1959	Mechanical Engineering
Case Western Reserve University, Cleveland, OH	MS	1966	Bioengineering
Case Western Reserve University, Cleveland, OH	PhD	1970	Structures/Mechanical Design

## RESEARCH AND PROFESSIONAL EXPERIENCE

1994 - present	Senior Bioengineering Consultant, BTI Consultants, Tempe, AZ. Assistive Devices, Biomechanics, Development of Composite Materials, Stress Analysis, Failure Analysis.
1994 - 1998	V.P. of Engineering, Orthologic Corporation, Tempe, AZ. Fracture fixation devices, bone growth stimulators.
1984 - 1994	Head of Bioengineering Division, Harrington Arthritis Research Center, Phoenix, AZ. Development of assistive devices, orthopedic implant design and testing, finite element analyses.
1981 - 1983	President, Paulson Medical Devices, Inc., Erie, PA. Development of fracture fixation devices and orthopedic implants.
1974 - 1981	Head of Bioengineering Division, Lord Corporation, Erie, PA. Development and manufacture of orthopedic implants. Composite material development.
1970 - 1974	Bell Telephone Laboratories, Columbus, OH. Development of Piezoelectric switching devices.
1960 - 1964	Reactor Engineer, U.S. Atomic Energy Commission, Argonne, IL.
1959 - 1960	Reactor Engineer, Argonne National Laboratory, Idaho Falls, ID.

## PUBLICATIONS

Recipient of 16 patents, co-author of 22 publications and over 115 presentations at technical society meetings. Seven relevant publications listed below:

J.B. Koeneman and J.S. Kaiser, "A Functional Evaluation of the DataHand® Key Entry System User Experience Evaluated By Questionnaire," RESNA, 1994.

J.B. Koeneman and C. Eblen, "A Longitudinal Evaluation of Four-Wheeled Walker: Effects of Experience," Topics in Geriatric Rehabilitation, 8(3)3, 1993.

J.B. Koeneman, "Advanced Materials for Assistive Devices," Topics in Geriatric Rehabilitation, Vol. 8, No. 2, December 1992.

J.B. Koeneman, with others, "A Multi-Dimensional Evaluation of a Four-Wheeled Walker," Assistive Technology, Vol. 4, No. 1, 1992.

J.B. Koeneman, N. Reich, P. Otten, and J. Kaiser, "Clothing for Special Needs; An Information Arena," 10<sup>th</sup> Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman and M. Phillips, "Composite Materials for Rehabilitation Devices," 10<sup>th</sup> Annual RESNA Conference, San Jose, CA, 1987.

J.B. Koeneman, "State of the Art of Finite Element Analysis in Orthopaedics," Materials Research Society, Proceedings of Medical Devices and Materials Symposium, 1987.

## AWARDS

International Fellow of Biomaterials Science and Engineering; International Union of Societies for Biomaterials Science and Engineering (1999)

Clemson Award for Contributions to the Literature, Society for Biomaterials (1997)

Fellow of Society for Advancement of Material and Process Engineering International (SAMPE) (1992)

Chapter Fellow Award, Society for Advancement of Materials and Process Engineering (SAMPE) (1990)

Engineer of the Year Award, Erie Engineering Society Council (1982)

## EXHIBIT C

Koeneman, James Bryant

## BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.  
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE		
Steven L. Wolf, Ph.D., FAPTA	Professor		
EDUCATION/TRAINING ( <i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i> )			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Clark University, Worcester, MA	BA	1965	Biology
Boston University, Boston, MA	MS	1969	Physical Therapy
Emory University, Atlanta, GA	MS	1972	Anatomy
Emory University, Atlanta, GA	PhD	1973	Anat/Neurophysiology
Karolinska Institute, Stockholm, Sweden	Postdoctoral	1973-75	Neurophysiology

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

## RESEARCH AND PROFESSIONAL EXPERIENCE

1969-70 Instructor, Anatomy and Physiology, Boston University, Boston, MA  
 1975-88 Principal Investigator, Emory University Rehab. Research & Training Center, Atlanta, GA  
 1975 Assistant Professor, Dept. of Surgery, Emory University School of Medicine, Atlanta, GA  
 1975-85 Assistant Professor, Dept. Anatomy, Emory University School of Medicine, Atlanta, GA  
 1975-78 Assistant Professor, Dept. of Rehab. Med., Emory University School of Medicine, Atlanta, GA  
 1978-85 Associate Professor, Dept. of Rehab. Med., Emory University School of Medicine, Atlanta, GA  
 1985-Present Professor, Dept. of Rehabilitation Medicine, Emory University School of Medicine, Atlanta, GA  
 1988-2000 Director of Research, Dept. of Rehab. Med., Emory University School of Medicine, Atlanta, GA

## HONORS

Marian Williams Research Award, 1980  
 Georgia Merit Award, Physical Therapy Association of Georgia, 1983  
 Golden Pen Award, American Physical Therapy Association, 1983  
 Catherine Worthingham Fellow of the American Physical Therapy Association, 1987  
 Outstanding Research Contributor to Advancing the Understanding of Biofeedback Mechanisms, Association of Applied Psychophysiology and Biofeedback, 1987  
 President, Association of Applied Psychophysiology and Biofeedback, 1991-92  
 Helen J. Hislop Award for Outstanding Contributions to Professional Literature, American Physical Therapy Association, 1993  
 Award of Excellence, Section on Clinical Electrophysiology, American Physical Therapy Association, 1993  
 Steven J. Rose Memorial Lectureship, Washington University, St. Louis, Missouri, 1994  
 Lucy Blair Service Award, American Physical Therapy Association, 1996  
 First John V. Basmajian Lectureship, International Society of Electrophysiology and Kinesiology, 1996  
 Section on Geriatrics, APTA, Outstanding published paper award, 1997.  
 Neurology Section, APTA, Outstanding Researcher Award, 1998.

## EXHIBIT C

Koeneman, James Bryant

Dr. Steve Wolf Appreciation Day, February 11, 1998, Warner-Robbins, Georgia: Outstanding Contributions to Rehabilitation in Georgia.

Lester Duplechen Outstanding Faculty Teacher Award, Department of Rehabilitation Medicine, 1999.

Stroke Council, American Heart Association, 1999.

APTA Mary McMillan Lecturer, 2002

### **SELECTED RELEVANT PUBLICATIONS (from over 200)**

- Wolf SL, Catlin PA, Ellis M, et al: Assessing the Wolf motor function test as an outcome measure for research with patients post-stroke. *Stroke*, 2001, in print.
- Sathian K, Greenspan A, Wolf SL: Doing it with mirrors - a novel approach to stroke rehabilitation. *J. Neural Repair and Neuroscience*, 14:73-76, 2000.
- Wolf SL, Catlin PA, Ellis M, Link A, Morgan B, Piacentino A: Assessing the Wolf motor function test as an outcome measure for research with patients post-stroke. *Stroke*, 2000, submitted for publication.
- Baer HR, Wolf SL: The modified Emory Functional Ambulation Profile: An outcome measure for the rehabilitation of post-stroke gait dysfunction. *Stroke*, 32:973-979, 2000.
- Kressig RW, Wolf SL, Sattin RW, O'Grady M, Greenspan A, Curns A, Kutner M: Associations between demographic and functional characteristics to activity-related fear of falling among older adults transitioning to frailty. *J Amer Geriatr Soc*, 2001, in print.
- Griffith, JS Kreutzer, B Pentland (eds), *Rehabilitation of the Adult and Child with Traumatic Brain Injury*, third edition, FA Davis, Philadelphia, 2000.
- Blanton S, Wolf SL: Effectiveness of upper extremity constraint-induced movement therapy on a patient with sub-acute stroke. *Physical Therapy*, 79:847-853, 1999.
- Wolf SL, Catlin PA, Bonner B, Marks M, Weston M: Up-training loading responses in older adults. *Applied Psychophysiology and Biofeedback*, 24: 179-195, 1999.
- Blanton S, Porter L, Smith D, Wolf SL: Strategies to enhance mobility in traumatic brain injured patients. In M. Rosenthal, ER
- Wolf SL, Gregor RJ: Exploring unique applications of kinetic analyses to movement in older adults. *J. Applied Biomechanics*, 15:75-83, 1999.
- Blanton SR, Wolf, SL: Effects of constraint-induced movement therapy intervention on individuals with upper extremity hemiparesis. *Neurology Report*, 1998, 22:164.
- Taub E, Wolf SL: Constraint induction techniques to facilitate upper extremity use in stroke patients. *Topics in Stroke Rehabilitation*, 4:38-61, 1997.
- Edgerton VR, Wolf SL, Levendowski DJ: Theoretical basis for patterning EMG amplitudes to assess muscle dysfunction. *Medicine and Science Sports and Exercise*, 28:744-751, 1996.
- Edgerton VR, Wolf SL, Levendowski DJ, Roy RR: Evaluating patterns of EMG amplitudes for trunk and neck muscles of patients and controls. *International J. Rehabilitation and Health*, 2:1-18, 1996.
- Edgerton VR, Wolf SL, Levendowski DJ: Theoretical basis for patterning EMG amplitudes to assess muscle dysfunction. *Medicine and Science Sports and Exercise*, 28:744-751, 1996.
- Wolf SL, Segal RL, Catlin PA, Kantos H, Pate P, Raleigh T, Tschorn J: Determining consistency of elbow joint threshold angle in spastic elbow flexor muscles. *Phys. Ther.*, 76:586-600, 1996.
- Wolf SL, Segal RL: Downtraining human biceps-brachii spinal stretch reflexes. *J. Neurophysiol.*, 75:1637-1645, 1996.
- Wolf SL, Segal RL, Heter ND, Catlin PA: Contralateral and long latency effects of human biceps brachii stretch reflex conditioning. *Exp. Brain Res.*, 107:96-102, 1995.
- Wolf SL, Catlin PA, Blanton S, Edelman J, Lehrer N, Schroeder D. Overcoming limitations in elbow movement in the presence of antagonist hyperactivity. *Phys. Ther.*, 74:35-44, 1994.
- Wolf SL, Barton LA: Learned nonuse in the hemiplegic upper extremity. In Gordon WA (ed), *Advances in Stroke Rehabilitation*. Anover Medical Publishers: Boston, 1993, pp. 79-86.
- Wolf SL, LeCraw DE, Barton LA, Jann BB: A comparison of motor copy and targeted feedback training techniques for restitution of upper extremity function among neurologic patients. *Phys Ther*, 69:719-735, 1989.

## EXHIBIT C

Koeneman, James Bryant

- Wolf SL, LeCraw DE, Barton LA, Jann BB: Forced use of hemiplegic upper extremities to reverse the effect of learned non-use among chronic stroke and head injured patients. *Exp Neurol*, 104:125-132, 1989.
- Evatt ML, Wolf SL, Segal RL: Modification of human spinal stretch reflexes: Preliminary studies. *Neurosci Letters*, 105:350-335, 1989.
- Wolf SL, Binder-Macleod SA: EMG biofeedback applications to the hemiplegic patient: Changes in upper extremity neuromuscular and functional status. *Phys Ther*, 63:1393-1403, 1404-1413, 1983.



**BIOGRAPHICAL SKETCH**

NAME		POSITION TITLE	
Christina M. Kwasnica M.D.		Director of Brain Injury Rehabilitation	
EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
University of Arizona Tucson, AZ	BA	1991	Political Science
Northwestern University Medical School Chicago, IL	MD	1995	Medicine

**POSITIONS:**

Resident Physician Northwestern University Medical School/Rehabilitation Institute of Chicago Department of Physical Medicine and Rehabilitation Chicago, IL 1995-1999

Clinical Instructor and Cognitive Neurology Fellow Northwestern University Alzheimer's Disease Center Departments of Neurology and Physical Medicine and Rehabilitation Chicago, IL 1999-2000

Director of Brain Injury Rehabilitation Barrow Neurological Institute Phoenix AZ 2000-present

**PROFESSIONAL AFFILIATIONS:**

Diplomate, American Board of Physical Medicine and Rehabilitation

Fellow, American Association of Physical Medicine and Rehabilitation

Diplomate, Association of Academic Physiatrists

**AWARDS AND HONORS:**

Seabury Foundation Endowed Research Resident- July 1998-June 1999

NIH National Research Service Award Fellowship- F32 NS10858-01 August 1999-August 2000

Sara Baskin Award for Research Excellence- Rehabilitation Institute of Chicago- May, 1999

President's Citation- 62<sup>nd</sup> Annual Assembly of the American Academy of Physical Medicine and Rehabilitation- for outstanding paper presentation- "Predictors of Ambulation in Stroke Rehabilitation"

**RESEARCH PROJECTS ONGOING OR COMPLETED DURING THE LAST THREE YEARS:***Current*

Predictors of Ambulation in Stroke Rehabilitation with Dr. Richard Harvey, Rehabilitation Institute of Chicago

*Pending*

Unilateral Neglect and the Relationship of Measurements with Function

*Prior*

Bromocriptine in Unilateral Neglect- F32 NS10858-01

NIDRR Stroke Research and Training Center- Rehabilitation Institute of Chicago

**PEER REVIEWED PUBLICATIONS:**

Kwasnica, CM and Heinemann, A. "Coping with Traumatic Brain Injury: Representative Case Studies," Archives of Physical Medicine and Rehabilitation, April 1994, 384-389.

Grujic, Z, Mapstone, M, Gitelman, D, Weintraub, S, Johnson, N, Hays, A, Kwasnica, CM, Harvey, RL, and Mesulam, M. "Dopamine Agonists Reorient Visual Exploration Away from Neglected Hemisphere," Neurology, December 1998.

Kwasnica, CM. "Unilateral Neglect after Right Hemisphere Stroke- a Review of the Syndrome and Management," Critical Reviews in Physical Medicine and Rehabilitation, accepted for publication December, 2000.

**SELECTED RECENT ABSTRACTS AND PRESENTATIONS:**

Kwasnica, CM, Harvey, RL, and Mullarkey, C. "Predictors of Ambulation in Stroke Rehabilitation," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 2000

Kwasnica, CM, Cherney, L, and Harvey, RL. "Unilateral Neglect and Relationships with Functional Outcomes," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 1998.

Kwasnica, CM, Grujic, Z, Mapstone, M, and Harvey, RL. "Bromocriptine Effect on Unilateral Visual Neglect After Right Hemisphere Infarct: A Pilot Study," Presented at the American Academy of Physical Medicine and Rehabilitation annual meeting, November, 1997.

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Assembly of the American Academy of Physical Medicine and Rehabilitation, November, 1998.

Managing Neglect Syndrome after Stroke: A Complete Experience- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago, April 1999

Pharmacology of Brain Injury- Rehabilitation Institute of Chicago- December 2000

Non-traumatic Brain Injury- Rehabilitation Institute of Chicago- December 2000

Pharmacologic Approaches to Motor Recovery after Stroke- Annual Multidisciplinary Stroke Course- Rehabilitation Institute of Chicago- April 2000

Atypical Dementias- Grand Rounds- Ingalls Hospital- Chicago, IL- April 2000

Neuroplasticity and Rehabilitation- Grand Rounds- Rehabilitation Institute of Chicago- July 2000

**BIOGRAPHICAL SKETCH**

NAME		POSITION TITLE	
Douglas E. Wendelboe		Software Consultant; President, Penn Microsystems	
EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Pennsylvania State University, State College, PA	BS	1972	Electrical Engineering
University of Pennsylvania, Philadelphia, PA	MS	1976	Electrical Engineering

**RESEARCH AND PROFESSIONAL EXPERIENCE**

1998-Present	Software Consultant, BTI Consultants, Tempe, AZ. Design of hardware and software for medical devices
1981-Present	President, Penn Microsystems. Consulting on microprocessor-based products. Medical device projects include: <ul style="list-style-type: none"> <li>• Hand-held Blood Prothrombin-Time Measuring Device, San Jose, CA, 2000-Present</li> <li>• Designed and implemented the Automated Calibration and Test System for the Bone Growth Stimulator, Phoenix, AZ, 1999-2000</li> <li>• Firmware enhancements for an electromagnetic Bone Growth Stimulator, Phoenix, AZ, 1997-1999</li> <li>• Developed an Automated Active Burn-In System for the Bone Growth Stimulator, Phoenix, AZ, 1996-1997</li> <li>• Designed and implemented firmware for Nerve Integrity Monitor Instrument, Jacksonville, FL, 1994-1995</li> <li>• Designed, implemented, and maintained the firmware for a line of Micro-titer Plate Readers, Winooski, VT, 1982-1985</li> <li>• Designed and implemented the complete firmware for a Pacemaker Systems Analyzer, Winooski, VT, 1980-1981</li> </ul>
1977-1981	Senior Associate Engineer, IBM Corp., Essex Junction, VT
1976-1977	Senior Product Engineer, Honeywell Corp., Ft. Washington, PA
1972-1976	Design Verification Software Engineer, UNISYS (Sperry-Univac), Blue Bell, PA

**PROFESSIONAL PUBLICATIONS**

"Recommended Use of the PL/M Computer Language in Safety-Related Systems," Report for the Nuclear Regulatory Commission, NUREG/CR-6463, June 1996  
Co-publisher of the Annual "Arizona High Tech Directory"  
Columnist for the "Arizona High Tech Times" newspaper

**PROFESSIONAL**

IEEE Computers, IEEE Software, IEEE Management, IEEE Biomedical  
American Society for Quality

**TECHNICAL SKILLS**

Languages: Keil C51 w/uVision2, IAR C, PIC-C, 8051, 8x86, 68xx, 68xxx assembler, Microchip PIC, Hitachi H8 assembler, TMS320C54x Algebraic assembler, National Instruments LabWindows/CVI, Microsoft Visual C++, Visual Basic  
RTOS: uC/OS-II, QNX, Keil RTX-51, familiarity with VxWorks, Tornado  
Microprocessors: Intel 8051, 80251, 8X93x USB, Intel 80x86, 80188, 386EX, 68HC05, 68HC08, 68HC11, 68xxx family, Hitachi 6303, H8S/2134, Microchip PIC16C74, 16C65, ST Micro ST10F167/168  
In-Circuit Emulation: Intel ICE 8051, 8085, 80188, 80x86, Nohau EMUL51-PC: 80C552, 89C51RD2, Microchip PIC-Master & others  
Peripheral Buses: I<sup>2</sup>C, CAN v2.0, USB, Motorola SPI, Dallas Semiconductor interfaces  
Design Standards: IS-9001 Design Quality Standards, FDA (97-4179) Medical Device Quality Systems Standards, FDA 510(k), FDA Pre-Market Approval (PMA)  
Bus Boards: PC/104 Bus, STD Bus, VME Bus  
Logic: SPICE Simulation, Programmable Logic Compilers  
Network: TCP/IP, WATTCP  
Database: MS SQL7, Oracle, Informix

## EXHIBIT C

Koeneman, James Bryant**BIOGRAPHICAL SKETCH**

NAME	POSITION TITLE		
Edward J. Koeneman	Consultant		
EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
Arizona State University, Tempe, AZ	BSEET	1992	Electronic Engineering
Arizona State University, Tempe, AZ	MT	1994	Electronic Engineering

POSITIONS

1999-Present BTI Consultants, Consultant.  
 1997-1999 Adtron Corp., Mesa, Arizona. Product Manager, Data Storage Devices.  
 1997 PCI Medical, Phoenix, Arizona. Design Engineer, Medical Electronics.  
 1995-1997 Prescom Electronics, Mesa, Arizona. Chief Engineer, Contract Electronic Design and Manufacturing.  
 1988-1995 Harrington Arthritis Research Center, Phoenix, Arizona. Lab Coordinator for Orthopaedic Resident Projects, Mechanical Testing.

PEER REVIEWED PUBLICATIONS

Koeneman, E.J., J.A. Lerman, R.J. Haynes, J.B. Koeneman, W. B. Wong, "A Biomechanical Comparison of Gardner-Wells Tongs and Halo Device Used for Cervical Spine Traction," SPINE, Volume 19, Number 21, pp. 2403-2406, 1994.

Koeneman, E.J., N.R. Crawford, A.G.U. Brantley, C.A. Dickman, "An Apparatus Applying Pure Nonconstraining Moments To Spine Segments In Vitro," SPINE, Volume 20, Number 19, pp. 2097-2100, 1995.

SELECTED PRESENTATIONS

Koeneman, E.J., J.A. Lerman, J.E. Maisel, J.B. Koeneman, "Electromyographic Analysis of the Hockey Slapshot," Presented at 1994 Fall Meeting of the Biomedical Engineering Society.

AWARDS AND HONORS

IEEE Outstanding Student Achievement Award, 1993

**BIOGRAPHICAL SKETCH**

NAME		POSITION TITLE	
Donald E. Herring		Senior Industrial Design Consultant	
EDUCATION (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY
American University, Washington, DC	BA	1967	Govt. and Public Admin.
Arizona State University, Tempe, AZ	BS	1982	Product Design
Arizona State University, Tempe, AZ	MSD	1993	Human Factors and Design

**PROFESSIONAL EXPERIENCE**

2001-Present	Senior Industrial Design Consultant, BTI Consultants, Tempe, Arizona
1998-Present	Assistant Professor, Arizona State University, Tempe, Arizona
1997-1999	Proprietor, Redfish Design, Phoenix, Arizona
1994-1997	Assistant Professor, Purdue University, West Lafayette, Indiana
1992-1994	Exhibit and Industrial Designer, Sunbelt Scenic Studios, Inc., Tempe, Arizona
1991-1992	Exhibit Designer, Giltspur Exhibits, Phoenix, Arizona
1982-1989	Senior Project Designer, Mattel Toys, Hawthorne, California
1975	Arizona Real Estate Sales and Brokerage, Phoenix, Arizona
1973	Specialist, United States Treasury Department, Washington, D.C.
1972	Foreman, Athens Paint & Drywall Company, Alexandria, Virginia
1968	OJT Contract Writer, Washington Urban League, Washington, D.C.
1968	Capitol Policeman, United States Capitol Building, Washington, D.C.

**PRINCIPAL PROFESSIONAL PUBLICATIONS AND PRESENTATIONS**

- "Children's Computer Human Factors and Seating Recommendations" (For Our Greatest Future Resource), Natural Resources, 1995  
 IDSA Design Education Conference Proceedings, Santa Fe, New Mexico, September 1995  
 "Twenty Years Later: What Are the 11982 Graduates of an Industrial Design Program Doing in the New Millennium?," Gumbo, 2000  
 IDSA Design Education Conference Proceedings, New Orleans, Louisiana, September 2000

**MEMBERSHIPS IN SCIENTIFIC AND PROFESSIONAL SOCIETIES**

- Human Factors and Ergonomics Society of America  
 Arizona Chapter Member of the Human Factors and Ergonomics Society of America  
 Industrial Design Society of America (IDSA)  
 The Arizona IDSA Chapter Secretary (Founding member and officer)  
 The Indiana IDSA Chapter Secretary/Treasurer (Resigned, April, 1997)

**PATENTS**

- U.S. Patent 4,787,876 - Toy Musical Play Set, 11/29/88, assigned  
 U.S. Patent 4,673,373 - Transformable Toy Block, 6/16/87, assigned  
 U.S. Patent 4,645,471 - Busy Ball Child's Toy, 3/7/85, assigned

**AWARDS, SCHOLARSHIPS AND HONOR SOCIETIES**

- Netherlands Toy of the Year Award to Disney Pots and Pans Band based on Originality, Safety and Suitability, 1988  
 Second Place Award (\$2,000.00) in Mattel's Toy of the Year Contest for the Invention and Development of the Double Dooz Transformers Toy Line, 1986  
 Nominated for the Mattel Toys Presidents Award for Leading a "Brainstorming Event" with 40 Participants Producing 100 Product Concepts for Presentation in Ten Days, 1985  
 Mattel \$2000.00 Discretionary Award for "The First Innovative Preschool Product Line to Come out of Mattel in Eight Years," 1985  
 Arizona State University Outstanding Senior Industrial Design, 1982  
 Honorable Mention (\$250.00) in Mattel Toy Design Contest, 1982  
 Awarded Internship at Mattel Toys, 1982  
 Phi Kappa Phi National Honor Society, 1982

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Cristobal Neal Eblen, Ph.D.		POSITION TITLE Director of Planning, Research and Program Evaluation	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Marist College	BA	1976	Psychology
Marist College	MA	1978	Community Psychology
Arizona State University	Ph.D.	1987	Social Psychology

**NOTE:** The Biographical Sketch may not exceed four pages. Items A and B may not exceed two of the four-page limit.

**A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

Post-doctoral Research Fellow (Harrington Arthritis Research Center) 1987-89  
 Psychologist I (AZ Department of Corrections) 1989-90  
 Psychologist II (Arizona State Hospital) 1990-91  
 Research and Statistical Analyst III (AZ Division of Behavioral Health Services) 1991-93  
 Psychologist II (Southern Arizona Mental Health Center) 1993-96  
 Psychologist II (AZ Department of Corrections) 1996-97  
 Research Associate (Community Partnership of Southern Arizona) 1997-2000

**B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.

Eblen, C. & Koeneman, J. (1993). A longitudinal evaluation of a four-wheeled walker: Effects of experience. Topics in Geriatric Rehabilitation, 8, 65-72.

Eblen, C. (1992). Evaluation of assistive devices. Topics in Geriatric Rehabilitation, 8, 6-11.

Eblen, C. & Koeneman, J. (1991). A multi-dimensional evaluation of a four-wheeled walker. Assistive Technology, 3, 32-37.

**C. Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of principal investigator identified above.

N/A

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## RESOURCES

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**FACILITIES:** Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

**Laboratory:**

KMI leases 1,433 square feet of office and laboratory space. Our lab contains the latest in hardware support tools such as: Logic analyzers, analog & digital oscilloscopes; I2C, USB and CAN bus analyzers; Internet server with TCP/IP tools. We also maintain the latest in software compilers, assemblers, simulators, and other software development tools for microprocessors and systems.

We have a complete model shop for the development of prototypes. This includes saws, sanders drill press and a complete supply of hand tools. We have a complete drafting facility.

These facilities are dedicated to the development of the device described in this proposal and to extensions of the design.

**Clinical:**

All clinical evaluations will be done at the Barrow Neurological Institute (BNI) of St. Joseph's Hospital in central Phoenix. It was first accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF) in 1988. BNI has a state-of-the-art rehabilitation facility and participates in many clinical rehabilitation research studies. Space and equipment for the clinical evaluations will be available for this study.

**Animal:**

NA

**Computer:**

Various computer simulation programs such as AutoCAD, Photoshop, Illustrator, Humanoid, Perception Video Capture Hunamoid run on eight Pentium computers.

**Office:**

The office has complete facsimile, copying and printing facilities.

**Other:**

The KMI facility is adjacent to BTI Consultants that provides secretarial and technician support and miscellaneous consulting on an as needed basis.

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**MAJOR EQUIPMENT:** List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

See above.

## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

# INTRODUCTION

The comments that follow are in sequential response to the concerns expressed by the reviewers on the summary statement of the previous grant proposal. Their concerns are summarized, followed by our response. Where appropriate and relevant, the responses are numbered or lettered and the narrative page number where the total response can be found is given next. Additions in this proposal are in italics.

### **Points of Resume and Summary:**

- 1(Pages 22 - 25,) **Insufficient details about clinical trial protocol.** At the suggestion of the first reviewer we have changed the protocol to involve only able-bodied participants (caregivers and clinicians).
2. (Pages 22 - 24 ) **Need to better focus on design development and demonstration of usability and feasibility.** The study using caregivers and clinicians will measure and record usability, durability, effectiveness of the feedback means, acceptance of the treatment protocols, and safety.
3. (Pages 19, 22, 23) **Reliability of the EMG signals.** The variability of the EMG signals within a treatment and between treatments will be measured on able-bodied subjects.
4. (Pages 22 - 24) **Rationale for Training.** The questionnaires and focus group response from caregivers and clinicians will help evaluate and refine the treatment protocols.
5. (Pages 22, 24, 25 ) **Patient Safety.** A Data Safety Management Board (DSMB) was established to review protocols, progress reports, and any incidents.
6. (Page 24) **Six hours a day may be too long for stroke patients.** Again the response of the trial participants will evaluate this question. If this treatment time is too long, shorter treatment intervals over extended periods of time are also feasible with a take home device.
7. (Page 22) **Healthy subjects should be used.** We redesigned the study to follow this suggestion.
- 8 (Page 22) **Determine adverse events.** A DSMB was included in the study to monitor the pilot study.

### **Reviewer 1:**

- A. (Page 22 ) **Suggested using normal subjects.** We have changed the pilot study accordingly.
- B.(Pages 19, 22, 24, 25 ) **Safety.** We have added more descriptive information on safety features designed into the device, have added a DSMB, and limited the study to normal participants.
- C.(Page 19) **Force Measurement.** We have described our method of calibration of the force sensors and how torque about the wrist is determined
- D.(Pages 19) **Thumb considerations.** How the thumb is abducted and how it can be adjusted for each patient is described. Clinician reaction to this method of handling the thumb and the increased tone with wrist extension is sought in the study.
- E. **Use of block.** Since we are not using stroke patients, this task practice has been deleted.
- F. **Wolf Motor Function Test.** Deleted. since stroke patients are no longer included
- G.(Pages 22, 24, 25 )**Safety and Adverse Events.** See 5. and 8. above.

### **Reviewer 2:**

The comments by reviewer 2 are all good, valid and need to be addressed when the study is applied to patients. Other comments mirrored comments by reviewer 1 that are addressed above.

### **Reviewer 3:** Comments in addition to those of others.

- H. **Number of devices needed.** Six devices are needed. However to have devices under modification while some tests are ongoing, 12 devices will be made. The costs are included in the budget.
- I.(Pages 22, 24 ) **Detailed Engineering Characterization of the device.** A task is included to document the detailed engineering characteristics of the device.

J.(Pages 6-8) **Need person experienced with EMG.** Dr. Wolf has written over 30 articles involving EMG and has written a book on the subject. In addition he is a past board member of the Electrokinesiology Society and is an assoc. editor of JEM.

### **Reviewer 4:** Comments in addition to those of others.

K.(Page 23) **Lack of human interface and concern about compliance.** We will be evaluating these concerns.

L. **Medical insurance coverage?** This Important question is not germane now but will be a target goal evolving from the Phase II study.



## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

### RESEARCH PLAN

#### A. SPECIFIC AIMS

The **primary purpose** of this project is to improve the restoration of upper extremity physical function of stroke patients by incorporating into one device, the treatment modalities of repetitive practice, and force and electromyographic (EMG) biofeedback. Each of these components may in and of itself demonstrate varying degrees of success in treating stroke patients. The device will assist therapy by supplying increased amounts of information to the physician and therapist while reducing the amount of patient contact time. The device will be adaptable to accommodate the changing paradigm of cerebrovascular accident (CVA) rehabilitation service delivery and to assist in studies designed to refine therapy protocols. The **hypothesis** to be tested is whether it is feasible for this device to *provide a comfortable and safe method of therapy. The first step of sequential hypothesis testing is to demonstrate usability on a wrist and finger joint model. This first step will be deemed feasible and worthy of further exploration if detailed design verification measurements and the responses of normal test subjects indicate the device will be safe and acceptable by patients.*

The specific aims of this proposal are:

1. *Document the device design specifications and the patient safety and hazard analysis.*
2. *Document the response of non-affected people to use of the device.*
3. *Refine display methods, software protocols, and patient-device interactions.*

#### B. BACKGROUND AND SIGNIFICANCE

Many people have movement disabilities caused by disease or injury. Among the causes are cerebrovascular accident or stroke (CVA), traumatic brain injury, multiple sclerosis, spinal cord injury and Parkinson's disease. This project focuses on stroke; however the results will have application to other causes of movement disability. Stroke is the leading cause of disability in the United States with at least 700,000 new cases each year [1-3]. Over half of these people have residual physical disability. Current stroke therapy is labor-intensive and costly. Often insurance does not cover the cost of full therapy. One estimate is that the United States spends \$30 billion per year to take care of stroke survivors. Seventeen billion dollars of this cost is direct medical expenditures and thirteen billion dollars represent an indirect cost due to lost productivity [3]. Another estimate is that the total direct and indirect costs of stroke are \$43.3 billion per year [3]. The number of strokes is projected to increase because of the increase in the over 50 "baby boom" population. Also, new pharmaceutical treatments for stroke are projected to increase the number of patients surviving a stroke and increase the percentage of stroke survivors requiring rehabilitation. Therefore, it is not surprising that a recent estimate indicates the prevalence of stroke will more than double over the next 50 years [2].

Because of health care reimbursement reductions, therapy time for stroke patients has been significantly decreased. Currently, a majority of time spent in therapy post-stroke concentrates on helping a patient adapt to their disability by teaching toileting skills and transfers. A consequence of this treatment is the emergence of, "learned nonuse" that hinders the restoration of available function [2]. Most current rehabilitation therapies are administered on a spaced basis. Recently, concentrated therapies have been developed that improve function in

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CVA patients by reversing the effects of "learned nonuse" [4]. Animal studies suggest that learned nonuse is established immediately after the initial organic damage. A patient is punished for trying to use the affected limb and is rewarded for using other parts of the body. Over time, healing of the organic damage occurs but the suppression of use learned in the acute phase remains in force [4]. As discussed by Taub [4], many of the therapies that have been shown to be effective in restoring function involve massed practice. Physical Therapy training techniques were used by Bach-y-Rita [5,6] and Franz, Scheetz, and Wilson [7]. Significant improvement in limb function was obtained in chronic CVA patients. Training techniques based on EMG biofeedback improved motor ability of chronic CVA patients, as demonstrated in studies by Wolf [8,9], Basmajian [10, 11], and Balliet [12]. Repetitive concentrated practice produced large therapeutic effects for lower limb function [13, 14, 15]. Taub (2,32) has systematically studied a variation of forced use of hemiplegic extremities, originally described by Wolf (31,35,36). Taub has labeled this therapy Constraint-Induced (CI) Movement Therapy [2, 32]. His group has shown positive results in controlled randomized studies [16]. Some of these experiments compared several massed therapy techniques and all showed very large increases in limb use over the treatment period.

Two very sophisticated robot systems are being developed for treatment and evaluation of CVA patients [1, 17]. These devices have shown some effectiveness in treatment of CVA patients and have developed very useful data for understanding recovery mechanisms; however, the current cost of these systems precludes their widespread clinical use [18].

Other studies show that measured EMG can be used to trigger neuromuscular electrical stimulation in restoring function to CVA patients [26, 27, 28, 29]. However, the discomfort of surface neuromuscular stimulation significantly limits the clinical implementation of this modality for persons with hemiplegia [34]. EMG biofeedback treatment of stroke patients has also shown some success [30, 31, 12, 8]. This treatment uses surface electrodes to capture the electrical activity of a selected muscle group. An electronic unit converts the signals into visual or audio information for the patient. This information is used by the patient to augment or decrease muscle activity.

A device that has a venerable history in supplying motion to assistive devices is the pneumatic artificial muscle. The artificial muscle exhibits many of the properties of human muscle. The device consists of an expandable internal bladder, e.g., a rubber tube, surrounded by a braided shell. When the internal bladder is pressurized, it expands radially against the braided shell. The pressure on the inside of the braid causes it to contract. Braided finger traps used to hold fingers on traction devices contract radially when pulled. The air muscle works in the same manner only in the opposite direction, i.e., increasing the diameter causes it to shorten. Like human muscle, the device has spring-like characteristics, is flexible, and is lightweight. The force-deflection characteristics can be made similar to those of human muscle. This type of device was first used in the 1950's for powered braces [19, 20]. Pressurized air canisters or accumulators that are recharged by air compressors supply air. Major advantages of the air muscle are its flexibility and ease of adaptation to address the specific loss of function exhibited by a patient. This type of device is often referred to as the McKibben Artificial Muscle. The device has three times the pull force of an air piston of the same cross sectional area. **The potential utility of this device resides in its unique combination of attributes: low cost, light-weight, low profile, and low noise operation.** The device has not been used extensively, because it has been applied in the wrong applications and has suffered from the lack of engineering in critical areas. Research on the application of the air muscle has been revived by the University of Washington [21, 22, 23, 24, 25]. The Shadow Organization in England uses the air muscle to operate biped and multiped robots [33].

### C. PRELIMINARY STUDIES

The labor-intensive and long treatment times of forced practice make effective rehabilitation expensive. A promising approach to providing a lightweight, low-cost stroke therapy device is a system that synergistically

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combines three modes of feedback that individually have been shown to be effective (visual presentation of desired motion, resistive-force of wrist flexor muscles and EMG activity of the extensor muscles). We have constructed a prototype of an air muscle powered therapy device for the fingers and wrist that has the adaptability to be used in current treatment modalities and also in the refinement of rehabilitation methods. Figure 1 is a drawing of the device. An air muscle is attached to the proximal forearm. Activation of the air muscle rotates a bar that extends the wrist and fingers and operates a *modified Watt six-bar* mechanism that extends the fingers. Wrist extension position is measured by a potentiometer that is incorporated in the device pivot. Resistance to extension is measured by force sensitive resistors (FSRs). Thus the FSR output is a measure of the resistance of finger and wrist flexor muscles. *The FSRs are calibrated after each device is assembled. A load cell is inserted between the activation bar on the mechanism and muscle. The mechanism is fixed in six different degrees of flexion-extension. The output of the FSRs is compared to the load cell output. The torque about the wrist at each wrist position is calculated by multiplying the muscle force by the distance to the line of action of the air muscle. Closely spaced surface electrodes measure wrist extensor EMG activity. The location of the EMG electrodes is determined for each patient by the therapist. The skin is rubbed 20 times with alcohol soaked gauze pads. The EMG output is used to measure the relative recruitment of selected extensor muscles and used to feedback the information to the patient to reinforce correct recruitment. Session to session variation in EMG values are recorded but we do not believe they will be a primary indicator of patient progress.*

### Wrist and Finger Motion

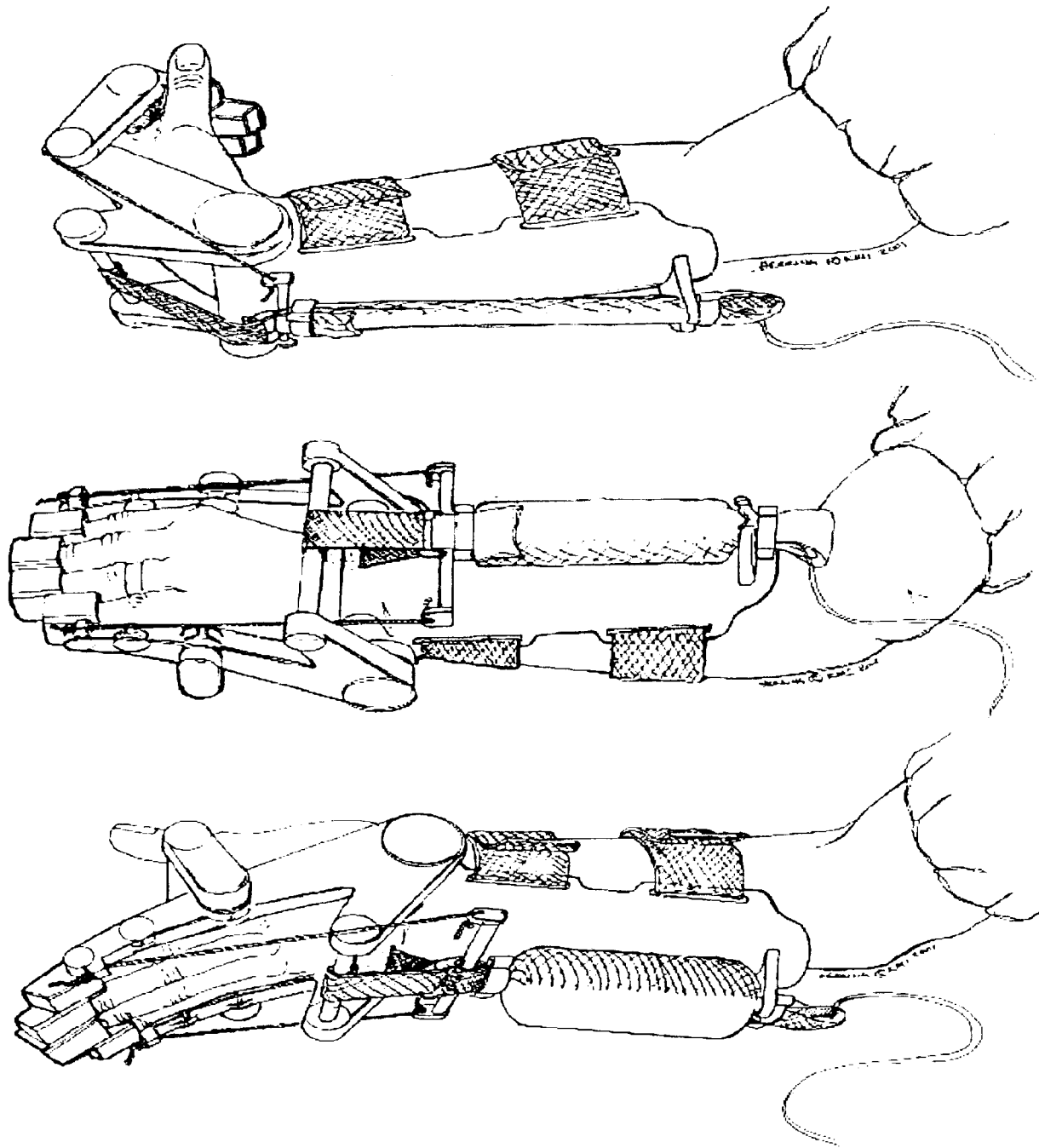
*The air muscle drives the fingers and wrist into extension by moving a mechanical linkage. The linkage is designed to move the fingers and wrist in a spiral fashion. Excessive force on the hand is prevented in several ways. A micro-compressor was chosen that has a maximum output pressure of 28 psi. This limits the maximum force supplied by the air muscle. The air muscle is a very compliant drive with the maximum force output at the fully flexed position where the stretch reflex resistance of the flexor muscles is minimum. As extension proceeds, the stretch reflex increases resistance to motion. If a large resistance is encountered during extension, the air muscle stretches and limits the range of motion. Since spastic flexor muscles are velocity sensitive, the velocity of actuation was chosen to be 5 degrees per second with no loading. With the weight of a flaccid hand this rate decreases to 3.8 degrees per second and with mild resistance the rate is 2.7 degrees per second. Experiments by Richard Herman showed only small increases in muscle tone occurred for very spastic hemiplegics due to velocity at rates below 6 degrees per second [40]. The rate in the KMI device is physically controlled by the volume capacity of the micro-compressor and the resistance in the pneumatic circuits. To prevent excessive extension of the wrist, a physical stop is also provided that limits motion of the activation bar at 60 degrees of wrist extension. A safety panic switch that releases the air pressure is also provided on a tether and is placed close to the subject's non-treating hand. An orthoplast® thumb splint is provided with the device. The fitting clinician can adjust the amount of abduction appropriate for a particular patient.*

A microprocessor controls the activation of the air muscle by operating the microcompressor and air valves. Wrist position is displayed as a bar graph on the LCD. The changing goal for active wrist motion is displayed as a line on the graph. One line of multi-color light emitting diodes (LEDs) indicates the degree of flexor resistance torque as measured by the force sensitive resistors. A second line of LEDs indicates the EMG activity of the wrist or finger extensors. The microcompressor, air valves, microprocessor, and the LCD are in a plastic box that sits on a table during therapy sessions. A coiled cable assembly that contains the electrical wires and air hose connects the box to the activation device. This system is a self-contained, mobile device that provides visual feedback of wrist and finger position, EMG extensor activity and wrist flexor resistive torque. The firmware in the microprocessor has been designed to be well-structured using object-oriented programming techniques. Use of these techniques yields more reliable code having fewer discrepancies and problems. Each of the object components was tested separately (component testing). When the firmware was integrated with

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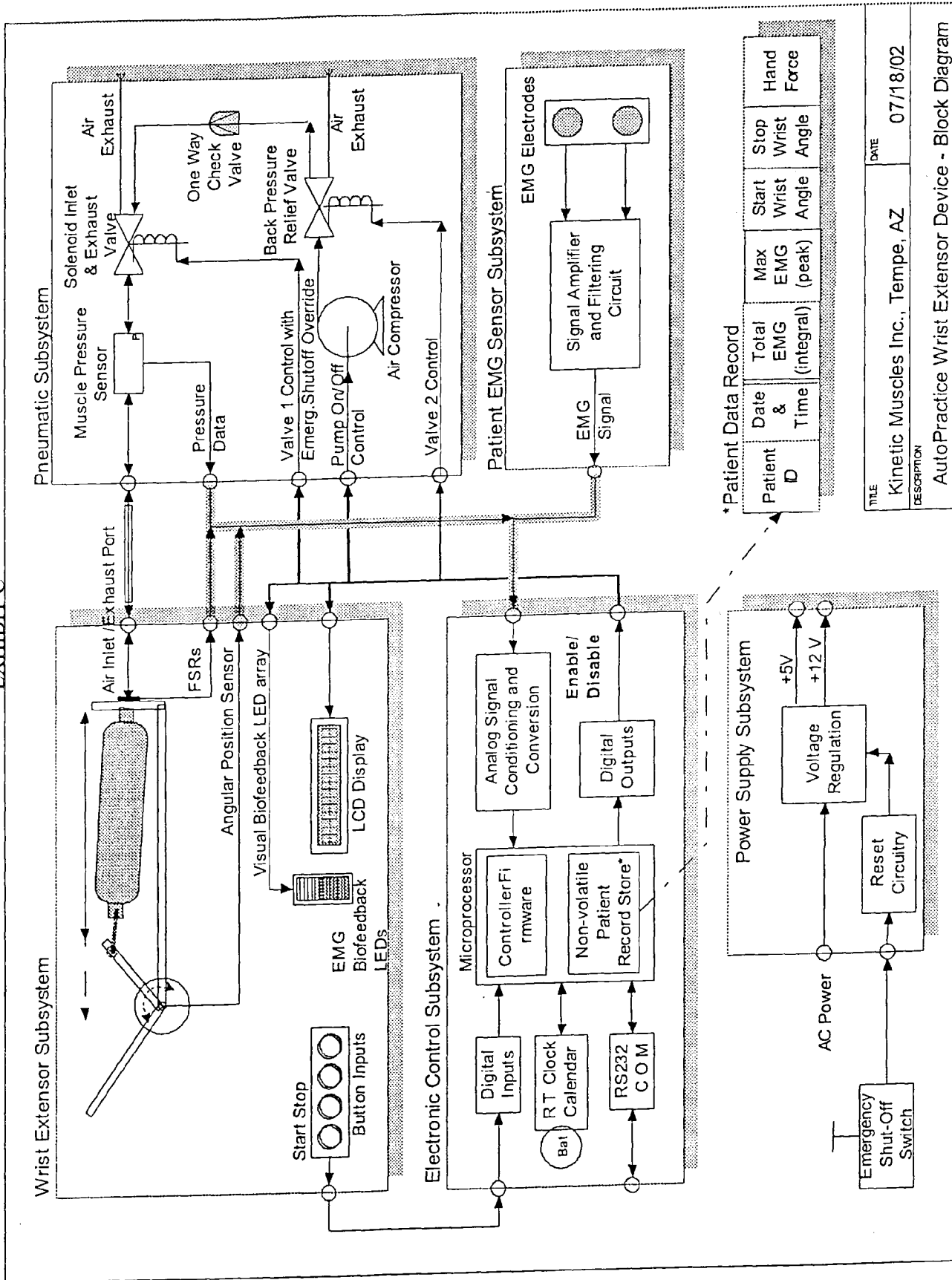
Principal Investigator/Program Director  
(Last, first, middle):

Koeneman, James Bryant



**Figure 1** Therapy Device in Flexion, Neutral and Extension;  
Shrouding, LEDs and Control Box not shown for Clarity

EXHIBIT C



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the electronic hardware, the complete system was tested (system integration testing). Finally, the operation of the complete device was validated and verified for function by comparing to the design requirements established at the project beginning. The essence of the design requirements is described in this proposal. A block diagram of the system is shown in Figure 2. The real-time clock/calendar is powered by a battery mounted on the printed circuit board when the power is off. The clock maintains the time and date continuously. Records of patient use, active range of motion, extensor resistive torque, and EMG activity are recorded with a time stamp in a non-volatile serial EEPROM memory device. Data is kept safe, even when no power is applied to the memory. These records can be downloaded to a Windows application on the therapist's personal computer. The results are sorted by participant and tabular and graphical displays made available for viewing.

### **H. EXPERIMENTAL DESIGN AND METHODS**

#### Device Characterization

*The purpose of this experiment is to characterize the pneumatic muscle. The characterization will be done by inflating a muscle thus contracting it, adding a sequence of loads and measuring the displacements of the muscle. This is repeated for different pressures of inflation. The experiment will include the testing of the passive force-length properties of the muscles, plugged and unplugged muscles and the reproducibility of muscles of the same type and length. In addition, full engineering characterization of the fully assembled device will be done.*

#### Pilot Study

*A pilot study of able-bodied participants will be conducted to determine the usability, safety and feasibility of using this device on stroke patients.*

Data Safety Monitoring Board (DSMB) – *This board will be established to review the progress of the study with a special interest in participant safety. Dr. Kwasnica, Dr. Wolf, Kay Wing, and Deborah Taylor will be on the board. They will review participant protocols, progress reports and any incident reports.*

Participant Population – *Five clinicians who treat stroke patients and five caregivers of stroke patients will be recruited. The clinicians will have a minimum of three years experience in treating stroke patients.*

Evaluation – *Deborah Taylor and Kay Wing, both licensed physical therapists will administer the program. The therapist will explain the operation and purpose of the device. A brochure describing the device and contact information will be provided the participant. The therapist will then place the EMG electrodes on the patient and attach them to the device. The therapist will demonstrate several treatments of the device. The device will be removed and the patient asked to attach the device and start treating without any help. The participants will be required to return after one week and at the end of two weeks for completion of questionnaires regarding acceptability of the device and evaluation of features. The participants will be asked their impression of the device weight and bulkiness, their fatigue during therapy, the effectiveness of the LED and LCD feedback methods, the reliability of the device and they will be asked to provide suggestions. Ratings will be on an ordinal scale.*

Protocol – *The participant is instructed to try to extend the wrist when a beep is heard. The EMG activity of the wrist extensors and the motion of the wrist are recorded in the memory of the device and displayed for the participant. The participant will be instructed to use the device for at least 6 hours a day, although more treatment is allowed. The treatments do not have to be continuous. The participant can start and stop the device at any time. The first 2 hours will emphasize EMG and joint position feedback. During the second 2 hours the flexor resistance torque from the flexors will be used as the feedback signal to help the patient reduce any flexor spasticity. The final 2 hours of therapy will have both extensor EMG and flexor resistance torque as*

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*achieved at the beginning of a day and at the end of each day is recorded in memory. This information will provide us with accurate information about participant compliance. The memory of the device will be downloaded onto a PC in the clinic. A summary chart graphically displaying the number of hours of use a day by the participant, the range of motion and the active range of motion by day will be displayed and the charts printed for the participant file.*

Data Analysis - Measures: There are three types of data collected in this study:

- (1) The number of hours of use per day by the participant. This is a measure of compliance with treatment.*
- (2) Recording, Displaying and Reporting of Functional Measures such as range of motion, EMG Biofeedback and flexor resistive muscle tone.*
- (3) Participant acceptance of the device as recorded in questionnaires and a final Focus Group.*

### Evaluation

*Participant acceptance of the device and suggested improvements will be entered into the design control system for the device for evaluation. Correlations will be calculated between reported compliance and actual hours of use.*

*The device will be considered acceptable and feasible if participant compliance is sufficient and the response to the questionnaires indicates that the device is useable and considered safe.*

Limitations – *While the numbers of minority and ethnic people in this study preclude statistically significant comparisons, the main purposes of this study are to refine the protocol and the device for a Phase II study and to investigate feasibility, acceptance and safety of this therapeutic device.*

Design Issues – The sensitivity of the EMG measurement to forearm motion and relative motion of muscles with respect to skin will be examined. The repeatability of placement of the electrodes from use to use will also be evaluated. Skin sensitivity to the pressure of the device or type of material will be examined.

Project Plan – *Three tasks will begin at the beginning of the project. Manufacture of the study devices will begin, the documentation to be provided to study participants will begin preparation, and development of innovative interactive treatment firmware will begin. Participant information kits will be sent to them describing the purpose and protocol of the study. Follow-up phone calls will be made to answer any questions and ascertain their willingness to participate in the study. Just before beginning the study, an extensive in-service session will be conducted for the therapists that will be conducting the patient training. Task 5 is the therapy portion of the study. Two clinician and two caregiver participants will begin treatment at the start of Task 5. After one week they will return for completion of questionnaires and debriefing. Then one week is scheduled for adjustment of the devices and firmware based on participant input. Then the three remaining clinicians and three caregivers will be given devices for one week of treatment. After their return and completion of questionnaires three weeks is scheduled for making adjustments in the devices and firmware. Then the two groups of two will return for another week of treatment. This week is followed by one week for*

## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

*adjustments and then the final group comes in for the beginning of one week of treatment. At the end of the study, a Focus Group will be held to have interaction between the participant therapists and caregivers in evaluating the device and providing further suggestions. A report of the Focus Group will document the participant's opinions of usability and safety of the device. Concurrent with the participant evaluations, performance characterization of the device, update of the hazard analysis and adjustments to the firmware and displays will be made. A final report addressing the feasibility of the device, device changes suggested by the results, and protocol changes suggested for the Phase II study will be prepared. Assuming feasibility is demonstrated, an application for Phase II funding will be prepared for December 1, 2003, submission.*

Table I Gantt Chart

ID	Task Name	Q2 '03			Q3 '03			Q4 '03	
		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
1	Device Manufacture	■	■	■					
2	Prepare Study Materials	■	■	■					
3	Study Clinician In-Service		■	■					
4	Patient Recruitment		■	■					
5	Pilot Study			■	■	■	■		
6	Focus Group						■		
7	Data Analysis				■	■	■		
8	Device Characteriation		■	■	■	■			
9	Interactive Tx Protocol Dev	■	■	■	■				
10	Final Report Preparation						■		
11	Phase II Proposal Submittal								■

*The deliverables of this Phase I study are: (1) a complete characterization of the device performance and hazard analysis, (2) refined displays, donning and doffing procedures and other device features that make the device user friendly, (3) the documented opinions of caregivers and clinicians as to usability, acceptance, and safety of the device.*

*The feasibility of using this device in a Phase II study involving stroke patients will be determined by the safety and usability conclusions.*

### E. HUMAN SUBJECTS

Involvement of Human Subjects: The purpose of the device under evaluation in this proposal is to facilitate the application of concentrated practice for stroke patients. Numerous studies, most notably by Taub and Wolf, have provided this therapy through one-on-one contact with physical therapists. In all of these studies there is no reason to believe that this intervention provides selective benefits (or limitations) based upon gender or racial attributes. In this study the gender and minority status will be recorded and reported for all participants. The numbers are so small that little meaningful statistical conclusions can be made although physiological and functional performance will be reported for these categories. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study.

Human Research Material: *Participants will be in two groups. Group I will be clinicians that have treated stroke patients for a minimum of three years. The identity of participants will be protected. Participants in this trial will receive codes to protect their identity throughout the study.*



## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

Recruitment of subjects: *The clinician participants will be recruited by the two physical therapists that are familiar with this device (Kay Wing and Deborah Taylor). The caregivers of stroke patients will be recruited by Dr. Kwashnica, Kay Wing, and Deborah Taylor.*

Potential Risks: The physical risk involved with using this device is overextending a joint and causing soft tissue damage. *To control this risk the range of motion of the mechanism is limited to the physiological range of motion of a normal person. To protect against overload of spastic muscles or contractures, the amount of force the device can provide is limited. A panic button is provided that removes load and shuts the device down.* Another risk is fatiguing the patient and causing anxiety. The risks involved with use of EMG electrodes are skin irritation. A control on this risk is that the participant has the right to drop out of the study at any time.

Minimization of Risk: The risk of overstretching a joint is controlled in several ways. There is a physical stop incorporated in the device that prevents wrist extension over 60°degrees of extension. If the wrist is stopped by an obstruction, the force is limited by the low stiffness of the air muscle actuator. Also, if the torque measured by the extension bar exceeds 8 newton meters (the resistive torque of the finger and wrist flexors), the air is exhausted and the device shut down. A panic button is also provided for easy access by the unaffected hand that will also exhaust the air muscle and shut the device down if the patient is feeling any discomfort, fatigue or anxiety.

Reasonableness of Risk: As noted above, effective means of controlling the risks are designed into the device. When one realizes that the eventual potential benefit to stroke patients can be substantially enhanced function in real world activities and improved quality of life beyond that achieved during the early rehabilitation interval, the risks are not significant.

FDA Approval: It is our opinion that this device is not a significant risk device and that only IRB approval is required. We will submit the protocol, a description of the device, a patient consent form, and an evaluation of the hazards involved in use of the device and how we are controlling these hazards to the IRB.

### **F. VERTEBRATE ANIMALS**

Not applicable.

### **G. LITERATURE CITED**

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Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

2. E. Taub, G. Uswatte, R. Pidikiti, "Constraint-Induced Movement Therapy: A New Family of Techniques with Broad Application to Physical Rehabilitation – A Clinical Review", *Journal of Rehabilitation Research and Development*, Vol. 36, No. 3, July 1999, pp 237-251.
3. G.E. Gresham, "Post-stroke Rehabilitation", U.S. Dept of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, May 1995, AHCPR publication # 95-0662.
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12. R. Balliet, B. Levy, K.M.T. Blood, "Upper Extremity Sensory Feedback Therapy in Chronic Cerebrovascular Inpatients with Impaired Expressive Aphasia and Auditory Comprehension," *Archives of Physical Medical Rehabilitation*, 1986, Vol. 61, pp. 301-10.
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14. S. Hesse, C. Bertelt, A. Schaffrin, M.S. Malezic, K-H. Mauritz, "Restoration of Gait in Nonambulatory Hemiparetic Patients by Treadmill Training with Partial Body-weight Support", *Archives of Physical Medicine and Rehabilitation*, 1994, Vol 75, pp. 1087-93.
15. S. Hesse, C. Bertelt, M.T. Jahnke, "Treadmill Training with Partial Body Weight Support Compared with Physiotherapy in Nonambulatory Hemiparetic Patients", *Stroke*, 1995, Vol. 26, pp. 976-81.
16. E. Taub, J.E. Crago, G. Uswatte, "Constraint-Induced Movement Therapy: A New Approach to Treatment in Physical Rehabilitation", *rehabilitative Psychology*, 1998, Vol43, pp. 152-70.
17. D. Reinkensmeyer, L.E. Kahn, M. Averbunch, A. McKenna-Cole, B.D. Schmit, W. Zev Rymer, "Understanding and Treating Arm Movement Impairment after Chronic Brain Injury: Progress with the ARM Guide," *Journal of Rehabilitation Research and Development* Vol. 27, No. 6, Nov/Dec 2000, pp. 653-662.
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Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

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34. J. Chae, R. Hart, "Comparison of Discomfort Associated with Surface and Percutaneous Intramuscular Electrical Stimulation for Persons with Chronic Hemiplegia", *Am J Phys Med Rehabil*, 1998, Nov-Dec, Vol. 77 No. 6, pp. 516-22.
35. C.G. Ostendorf, S.L. Wolf, "The effect of forced use of upper extremity of a hemiplegic patient on changes in function: a single case design", *Phys Ther* 62:1022-1028, 1981.
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## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

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### **H. CONTRACTUAL ARRANGEMENTS**

Dr. Wolf is participating at no cost with the anticipation that this study will lead to a device that is supportive of the treatments being studied in the EXCITE trial.

The applicant organization and St. Joseph's Medical Center/ St. Joseph's Medical Center are prepared to establish in writing the required contractual agreements whereby the clinical institutions will provide physician and therapist services as described in this proposal. The cost of providing these services is included in the budget of this proposal.

### **I. CONSULTANTS**

An Advisory Board for the project will provide advice and guidance on clinical issues, engineering, and product development. The members of the Advisory Board are:

- Dr. Steven Wolf, Ph.D., Professor of Rehabilitation Medicine at Emory University. Dr. Wolf is the principal investigator of a randomized national clinical trial to explore the effect of forced use therapy on patients who have sustained a stroke. He will be advising on the treatment and evaluation protocols and provide general guidance on the treatment of stroke patients.
- Deborah Koeneman has a MS degree in Bioengineering from ASU. She has worked for the Food and Drug Administration in regulation of Medical Devices. She currently is Director of Regulatory Affairs for OrthoLogic Corporation. She will consult on clinical trial, regulatory, and quality assurance issues.
- Don Herring, an Assistant Professor of Industrial Design at ASU, will consult on human factors, industrial design, and attachment design.
- Cristobel Eblen, Ph.D., Cris is a psychologist with experience in designing patient evaluation studies and questionnaires and performing statistical analyses.

EXHIBIT C



EMORY  
UNIVERSITY  
SCHOOL OF  
MEDICINE

Center for Rehabilitation Medicine  
Department of Rehabilitation Medicine

July 22, 2002

Mr. James B Koeneman, President  
Kinetic Muscles, Inc.  
1949 East Broadway Road  
Suite D  
Tempe, AZ 85282

Dear Jim:

I have read your revised SBIR proposal, "Development of a Massed Practice Stroke Therapy Device"(1 R43 HD41805-01A) regarding the application of your combined force feedback, EMG biofeedback, and pneumatic muscle instrumentation to facilitate improved movement and function in the wrists and digits of patients who have sustained a stroke but in whom movement initiation into extension exists. I believe you have responded admirably to the reviewers comments and that the decision to first field test your device using able-bodied individuals, is a wise one.

As you know, I have spent considerable time researching criteria for the use of EMG biofeedback applied to the upper extremities of patients after stroke. I have also done considerable work in the area of "forced use" or "constraint induced movement therapy" among stroke patients and currently am PI on the NIH funded EXCITE (EXtremity Constraint Induced Therapy Evaluation) national clinical trial. I will be more than honored to serve as a consultant to your project. I am very concerned that the potential to use multi-modal (muscle and force) physiological feedback be made optimal and researched with extreme vigor. I believe that your device will assist in the delivery of excellent product development and well-performed research. I am most impressed by your staff's commitment to this project.

Good luck with your efforts. Having read your proposal, I believe you have addressed all the reviewer comments comprehensively. If I can assist in any way during the final preparation of this proposal, please feel free to call upon me.

STEVEN L. WOLF, Ph.D., FAPTA, PT  
Professor, Department of Rehabilitation Medicine  
Professor of Geriatrics, Department of Medicine  
Associate Professor, Department of Cell Biology  
Director, Program in Restorative Neurology (PROREN)  
Emory University School of Medicine

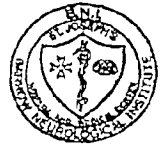


Emory University School of Medicine  
1441 Clifton Road NE  
Atlanta, Georgia 30322

The Robert W. Woodruff Health Sciences Center  
*An equal opportunity, affirmative action university*

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**Barrow Neurological Institute®**  
St. Joseph's Hospital and Medical Center



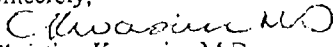
June 1, 2001

To whom it may concern:

This letter shall serve as a letter of support for the Small Business Innovation Research grant titled "Development of a Massed Practice Stroke Therapy Device." I am pleased to be asked to participate in the opportunity to engineer a device that may assist patients in applying the principles of massed practice in their stroke recovery.

As Director of Brain Injury Rehabilitation at Barrow Neurological Institute, I have the background to be able to participate in such research. I am looking forward to collaboration in this study.

Sincerely,

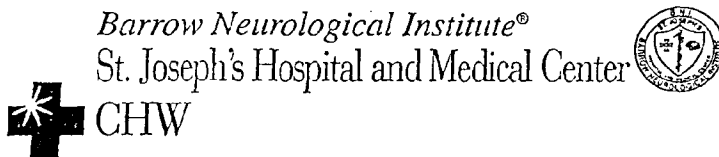
  
Christina Kwasnica M.D.  
Attending Psychiatrist  
Barrow Neurological Institute  
St. Joseph's Hospital & Medical Center  
Phoenix, AZ 85013

St. Joseph's Hospital  
and Medical Center



350 W. Thomas Road  
Phoenix, AZ 85013  
(602) 406-3000 or 1-800-BARROW-1  
<http://www.chw.edu/bni>

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the Sisters of Mercy



350 West Thomas Road  
Phoenix, AZ 85013  
602 406 3000 Telephone

March 29, 2001

James B. Koneman, Ph.D.  
1937 East Broadway Road  
Tempe, AZ 85282-1701

Dear Dr. Koneman:

The research project "Development of a Massed Practice Stroke Therapy Device" as submitted by BTI Consultants has the full administrative support and approval of our institution.

Catholic Healthcare West Arizona, dba St. Joseph's Hospital and Medical Center, is familiar with federal subcontract policies. Upon negotiation of a NIH subcontract, our institution will fully comply with those policies if the grant is awarded to BTI Consultants.

Sincerely,

A handwritten signature in cursive script that reads 'Toby L. Anchie'.

Toby L. Anchie, R.N., MAEd  
Executive Director, Research & Development

## EXHIBIT C

Principal Investigator/Program Director (Last, First, Middle): Koeneman, James, Bryant

## CHECKLIST

## TYPE OF APPLICATION (Check all that apply.)

☐ NEW application. (This application is being submitted to the PHS for the first time.)
☒ ☐ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No. \_\_\_\_\_ ☐ SBIR Fast Track  
☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. \_\_\_\_\_ ☐ STTR Fast Track
☒ REVISION of application number: 1R43HD041805-01A1

(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

☐ COMPETING CONTINUATION of grant number: \_\_\_\_\_

(This application is to extend a funded grant beyond its current project period.)

## INVENTIONS AND PATENTS

(Competing continuation appl. and Phase II only)

☐ No☐ Previously reported☐ Yes. If "Yes,"☐ Not previously reported☐ SUPPLEMENT to grant number: \_\_\_\_\_

(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of principal investigator/program director.

Name of former principal investigator/program director: \_\_\_\_\_

☐ FOREIGN application or significant foreign component.

## 1. PROGRAM INCOME (See instructions.)

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
	0	

## 2. ASSURANCES/CERTIFICATIONS (See instructions.)

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/certifications are provided in Section III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects; •Research Using Human Embryonic Stem Cells•  
 •Research on Transplantation of Human Fetal Tissue •Women and  
 Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals•

•Debarment and Suspension; •Drug-Free Workplace (applicable to new  
 [Type 1] or revised [Type 1] applications only); •Lobbying; •Non-  
 Delinquency on Federal Debt; •Research Misconduct; •Civil Rights  
 (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641  
 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age  
 Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and  
 Human Gene Transfer Research; •Financial Conflict of Interest (except  
 Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution  
 Participation.

## 3. FACILITIES AND ADMINISTRATIVE COSTS (F&amp;A)/ INDIRECT COSTS. See specific instructions.

☐ DHHS Agreement dated: \_\_\_\_\_☒ ☐ No Facilities And Administrative Costs Requested.☐ DHHS Agreement being negotiated with \_\_\_\_\_

Regional Office.

☐ No DHHS Agreement, but rate established with \_\_\_\_\_

Date \_\_\_\_\_

CALCULATION\* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

a. Initial budget period:	Amount of base \$ _____	x Rate applied _____	% = F&A costs \$ _____
b. 02 year	Amount of base \$ _____	x Rate applied _____	% = F&A costs \$ _____
c. 03 year	Amount of base \$ _____	x Rate applied _____	% = F&A costs \$ _____
d. 04 year	Amount of base \$ _____	x Rate applied _____	% = F&A costs \$ _____
e. 05 year	Amount of base \$ _____	x Rate applied _____	% = F&A costs \$ _____

TOTAL F&amp;A Costs \$

\*Check appropriate box(es):

☐ Salary and wages base☐ Modified total direct cost base☐ Other base (Explain)☐ Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

4. SMOKE-FREE WORKPLACE ☒ Yes ☐ No (The response to this question has no impact on the review or funding of this application.)



**Section E Human Subjects (addendum)*****Inclusion Plans for Women, Minorities & Children***

The targeted enrollment in the Pilot Study is in the following table. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study. See Involvement of Human Subjects on p. 24.

**Targeted/Planned Enrollment Table**

This report format should NOT be used for data collection from study participants.

**Study Title:** Pilot Study of Usability, Safety and Feasibility of Stroke Therapy Device

**Total Planned Enrollment:** 10

<b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	<b>Females</b>	<b>Males</b>	<b>Total</b>
Hispanic or Latino	1	0	1
Not Hispanic or Latino	6	3	9
Ethnic Category Total of All Subjects*	7	3	10
<b>Racial Categories</b>			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	2
White	6	2	8
Racial Categories: Total of All Subjects *	7	3	10

\*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

***Data & Safety Monitoring Plan***

Adverse events will be monitored during the clinical study to determine if there are any device-related adverse effects. As outlined on page 25 of this proposal, anticipated potential adverse device effects include overextension of the wrist and/or fingers, patient fatigue, and skin irritation under EMG electrodes. All anticipated adverse device effects will be reported to the Data Safety Monitoring Board (see p. 22) as they occur and a summary of all events will be supplied to the IRB and the NIH at the conclusion of the study.

*Seth e-mail 9/30/02*

## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

An *unanticipated adverse device effect* is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Investigators will be required to submit reports of unanticipated adverse device effects KMI, NIH and the reviewing IRB as soon as possible and no later than 10 working days after the investigator first learns of the effect.

KMI will submit results of evaluations of unanticipated adverse device effects to the FDA, NIH, IRB, and participating investigators within 10 working days after receiving notice of effect.

## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

adjustments and then the final group comes in for the beginning of one week of treatment. At the end of the study, a Focus Group will be held to have interaction between the participant therapists and caregivers in evaluating the device and providing further suggestions. A report of the Focus Group will document the participant's opinions of usability and safety of the device. Concurrent with the participant evaluations, performance characterization of the device, update of the hazard analysis and adjustments to the firmware and displays will be made. A final report addressing the feasibility of the device, device changes suggested by the results, and protocol changes suggested for the Phase II study will be prepared. Assuming feasibility is demonstrated, an application for Phase II funding will be prepared for December 1, 2003, submission.

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4	Patient Recruitment	■	■	■					
5	Pilot Study			■	■	■	■		
6	Focus Group						■		
7	Data Analysis				■	■	■		
8	Device Characteriation		■	■	■				
9	Interactive Tx Protocol Dev	■	■	■	■				
10	Final Report Preparation						■		
11	Phase II Proposal Submittal								■

The deliverables of this Phase I study are: (1) a complete characterization of the device performance and hazard analysis, (2) refined displays, donning and doffing procedures and other device features that make the device user friendly, (3) the documented opinions of caregivers and clinicians as to usability, acceptance, and safety of the device.

The feasibility of using this device in a Phase II study involving stroke patients will be determined by the safety and usability conclusions.

### E. HUMAN SUBJECTS

Involvement of Human Subjects: The purpose of the device under evaluation in this proposal is to facilitate the application of concentrated practice for stroke patients. Numerous studies, most notably by Taub and Wolf, have provided this therapy through one-on-one contact with physical therapists. In all of these studies there is no reason to believe that this intervention provides selective benefits (or limitations) based upon gender or racial attributes. In this study the gender and minority status will be recorded and reported for all participants. The numbers are so small that little meaningful statistical conclusions can be made although physiological and functional performance will be reported for these categories. Children less than 18 years of age are excluded because an immature nervous system may respond differently to this therapy than a mature one and the low number of young patients available for this short study.

Human Research Material: Participants will be in two groups. Group I will be clinicians that have treated stroke patients for a minimum of three years. The identity of participants will be protected. Participants in this trial will receive codes to protect their identity throughout the study.

## EXHIBIT C

Principal Investigator/Program Director (Last, first, middle): Koeneman, James, Bryant

recruitment of subjects: *The clinician participants will be recruited by the two physical therapists that are familiar with this device (Kay Wing and Deborah Taylor). The caregivers of stroke patients will be recruited by Dr. Kwasnica, Kay Wing, and Deborah Taylor.*

Potential Risks: The physical risk involved with using this device is overextending a joint and causing soft tissue damage. *To control this risk the range of motion of the mechanism is limited to the physiological range of motion of a normal person. To protect against overload of spastic muscles or contractures, the amount of force the device can provide is limited. A panic button is provided that removes load and shuts the device down.* Another risk is fatiguing the patient and causing anxiety. The risks involved with use of EMG electrodes are skin irritation. A control on this risk is that the participant has the right to drop out of the study at any time.

Minimization of Risk: The risk of overstretching a joint is controlled in several ways. There is a physical stop incorporated in the device that prevents wrist extension over 60° degrees of extension. If the wrist is stopped by an obstruction, the force is limited by the low stiffness of the air muscle actuator. Also, if the torque measured by the extension bar exceeds 8 newton meters (the resistive torque of the finger and wrist flexors), the air is exhausted and the device shut down. A panic button is also provided for easy access by the unaffected hand that will also exhaust the air muscle and shut the device down if the patient is feeling any discomfort, fatigue or anxiety.

Reasonableness of Risk: As noted above, effective means of controlling the risks are designed into the device. When one realizes that the eventual potential benefit to stroke patients can be substantially enhanced function in real world activities and improved quality of life beyond that achieved during the early rehabilitation interval, the risks are not significant.

FDA Approval: It is our opinion that this device is not a significant risk device and that only IRB approval is required. We will submit the protocol, a description of the device, a patient consent form, and an evaluation of the hazards involved in use of the device and how we are controlling these hazards to the IRB.

### **F. VERTEBRATE ANIMALS**

Not applicable.

### **G. LITERATURE CITED**

1. H.I. Krebs, B.T. Volpe, M.L. Aisen, N. Hogan, "Increasing Productivity and Quality of Care: Robot-aided Neuro-rehabilitation", Journal of Rehabilitation Research and Development, Vol. 37, No. 6, Nov/Dec, 2000, PP 630-652.

**EXHIBIT C**  
Principal Investigator/Program Director (Last, first, middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 7/01/04	THROUGH 6/30/05	
PERSONNEL ( <i>Applicant organization only</i> )		TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED ( <i>omit cents</i> )		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Richard Herman, MD	Principal Investigator	12	20.0	100,000	20,000	4,800	24,800
Vassia Roulia	Res Monitor	12	30.0	55,000	16,500	3,960	20,460
Therapist	Evaluator	12	50.0	61,167	33,584	8,060	41,644
Res. Coordinator	Clin. Res Coordinator	12	50.0	73,840	36,920	8,861	45,781
			0.0	0	0	0	0
<b>SUBTOTALS</b> →					<b>87,004</b>	<b>20,881</b>	<b>107,884</b>
CONSULTANT COSTS							0
EQUIPMENT ( <i>Itemize</i> )							0
SUPPLIES ( <i>Itemize by category</i> )							0
TRAVEL							
Nat'l Stroke Mtg							1,500
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					0
ALTERATIONS AND RENOVATIONS ( <i>Itemize by category</i> )							
OTHER EXPENSES ( <i>Itemize by category</i> )							
<b>SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b>							<b>\$109,384</b>
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS					
		FACILITIES AND ADMINISTRATIVE COSTS					0
<b>TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b> ( <i>Item 7a, Face Page</i> ) →							<b>\$109,384</b>
<b>SBIR/STTR Only: FEE REQUESTED</b>							

## EXHIBIT C

Form Approved Through 05/2004

OMB No. 0925-0001

Department of Health and Human Services Public Health Services <b>Grant Application</b> <i>Do not exceed character length restrictions indicated.</i>		<b>LEAVE BLANK—FOR PHS USE ONLY</b>	
Type		Activity	Number
Review Group		Formerly	
Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT (Do not exceed 56 characters, including spaces and punctuation.)			
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> YES (If "Yes," state number and title) Number: Title:			
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		New Investigator <input type="checkbox"/> No <input type="checkbox"/> Yes	
3a. NAME (Last, first, middle)		3b. DEGREE(S)	
3c. POSITION TITLE		3d. MAILING ADDRESS (Street, city, state, zip code)	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT			
3f. MAJOR SUBDIVISION			
3g. TELEPHONE AND FAX (Area code, number and extension) TEL: FAX:			
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes		5. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes	
4a. Research Exempt <input type="checkbox"/> No <input type="checkbox"/> Yes If "Yes," Exemption No.		5a. If "Yes," IACUC approval Date	
4b. Human Subjects Assurance No.		5b. Animal welfare assurance no.	
4c. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes			
6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY) From Through		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD	
		7a. Direct Costs (\$)	
		7b. Total Costs (\$)	
		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
		8a. Direct Costs (\$)	
		8b. Total Costs (\$)	
9. APPLICANT ORGANIZATION Name Address  Institutional Profile File Number (if known)		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged	
		11. ENTITY IDENTIFICATION NUMBER  DUNS NO. Congressional District	
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address  Tel: FAX: E-Mail:		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address  Tel: FAX: E-Mail:	
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PD NAMED IN 3a. (In ink. "Per" signature not acceptable.)	
		DATE	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. (In ink. "Per" signature not acceptable.)	
		DATE	

**EXHIBIT C**  
Principal Investigator/Program Director (Last, first, middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 7/01/04	THROUGH 6/30/05	
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
James Koeneman	Principal Investigator	12	30.0	120,000	36,000	8,460	44,460
Edward Koeneman	Engineering	12	30.0	100,000	30,000	6,900	36,900
Robert Schultz	Indust Des.	12	30.0	38,000	11,400	2,622	14,022
Pat Jacobson	Ops Mfg	12	20.0	80,000	16,000	3,680	19,680
TBN	ASU Intern	12	50.0	30,000	15,000	0	15,000
<b>SUBTOTALS</b> →					<b>72,400</b>	<b>13,202</b>	<b>85,602</b>
CONSULTANT COSTS							
Statitician							1,500
EQUIPMENT (Itemize)							
20 devices @ 3500, Dell650 Workstation 1800							71,800
SUPPLIES (Itemize by category)							
Software licenses, upgrades \$1000							
Electronics disks, cartridges \$500							
Electrodes & Supplies \$500							
Lab Supplies \$2500							4,500
TRAVEL							
Nat'l Stroke Mtg							1,500
PATIENT CARE COSTS		INPATIENT					
		OUTPATIENT					4,700
ALTERATIONS AND RENOVATIONS (Itemize by category)							
OTHER EXPENSES (Itemize by category)							
IRB Charges \$2200							2,200
<b>SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b>							<b>\$171,802</b>
CONSORTIUM/CONTRACTUAL		DIRECT COSTS					
COSTS		FACILITIES AND ADMINISTRATIVE COSTS 109K + 156*0.12 = 161,888					
<b>TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)</b> →							<b>\$ 333,690</b>
<b>SBIR/STTR Only: FEE REQUESTED</b> 7%							21,168

## EXHIBIT C

**Facilities and Administrative (F&A) Costs**

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS agency cost advisory office. If the applicant organization is in the process of initially developing or renegotiating a rate, or has established a rate with another Federal agency, it should, immediately upon notification that an award will be made, develop a tentative F&A cost rate proposal. This is to be based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS Guide for Establishing Indirect Cost Rates, and submitted to the appropriate DHHS Regional Office or PHS agency cost advisory office. F&A costs will NOT be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.



EXHIBIT C

Personnel		Role	Appt. type	%Effort	Inst. Sal.	Requested	Fringe	Subtotal	Totals
Name	PI								
Richard Herman, MD		Res Monitor	12	20	100,000	20,000	4,800	24,800	
Yassia Rouila		Res Monitor	12	30	55,000	16,500	3,960	20,460	
Therapist		Evaluator	12	50	67,157	33,584	8,060	41,644	
Res Coordinator		Clinical Res Coord	12	50	73,840	36,920	8,861	45,781	
Evaluator		WMFT/knr/fMRI	12	0	30,000	0	0	0	
Recruiter/Trainer		Rec/Train	12	0	35,000	0	0	0	
Kay Wing		Consult	12	0	60,000	0	0	0	
		Consult	12	0	80,000	0	0	0	
Personnel subtotal						87,004	20,881	107,884	107,884
						Fringe % GT	0.240		